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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 800,541	03 07 2001	Liselotte Bjerre Knudsen	6169.200-US	4130

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EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 10 02 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/800,541

Applicant(s)

KNUDSEN, LISELOTTE BJRRE

Examiner

David K. Kerner  
Elizabeth C. Kemmerer, Ph.D.

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1646 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 26-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 26-42 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

#### **37 CFR 1.126**

Applicant is advised that, in the new claim set submitted with Paper No. 9 (07 March 2001), two claims appeared with the number 41. The second claim 41 has been renumbered under 37 CFR 1.126 as claim 42.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 26-29 and 36-42, drawn to therapeutic method of administering GLP-1 agonist, classification dependent upon structure of agonist.
- II. Claim 30, drawn to therapeutic method of administering a GLP-1 agonist and a hormone compound, classification dependent upon structure of agonist.
- III. Claims 31 and 32, drawn to therapeutic method of administering a GLP-1 agonist and a non-GLP-1 agonist antihyperlipidemic agent, classification dependent upon structure of agonist.
- IV. Claim 33, drawn to therapeutic method of administering a GLP-1 agonist and an antihypertensive agent, classification dependent upon structure of agonist.
- V. Claim 34, drawn to therapeutic method of administering a GLP-1 agonist and an appetite-regulating agent, classification dependent upon structure of agonist.

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- VI. Claim 35, drawn to therapeutic method of administering a GLP-1 agonist and an antidiabetic agent, classification dependent upon structure of agonist.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires administration of a GLP-1 agonist alone, which is not required by any of the other groups. Invention II requires further administration of a hormone compound, which is not required by any of the other groups. Invention III requires further administration of an antihyperlipidemic agent, which is not required by any of the other groups. Invention IV requires further administration of an antihypertensive agent, which is not required by any of the other groups. Invention V requires further administration of an appetite-regulating agent, which is not required by any of the other groups. Invention VI requires further administration of an antidiabetic agent, which is not required by any of the other groups. The different methods would not be used in the same patient populations. For example, only a patient population suffering from high lipid levels *and* hypertension would be selected for the method of Group IV. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches

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for the three methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and potentially different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

**IF ANY OF GROUPS I-VI ARE ELECTED, A SPECIES OF GLP-1 AGONIST MUST BE ELECTED FROM THE FOLLOWING LIST:**

- a) Arg<sup>26</sup>,Lys<sup>34</sup>(N-ε-(γ-Glu(N-α-hexadecanoyl)))-GLP-1(7-37);
- b) Arg<sup>34</sup>,Lys<sup>26</sup>(N-ε-(γ-Glu(N-α-hexadecanoyl)))-GLP-1(7-37);
- c) exendin-3;
- d) exendin-4;
- e) Val<sup>8</sup>-GLP-1(7-37);
- f) Thr<sup>8</sup>-GLP-1(7-37);
- g) Met<sup>8</sup>-GLP-1(7-37); and
- h) Gly<sup>8</sup>-GLP-1(7-37).

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is an example of a generic claim.

**IF GROUP II IS ELECTED, A SPECIES FROM THE FOLLOWING LIST MUST ALSO BE ELECTED:**

- II-a) growth hormone;
- II-b) growth hormone releasing agent;
- II-c) prolactin; and
- II-d) placental lactogen.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 30 is an example of a generic claim.

**IF GROUP III IS ELECTED, A SPECIES FROM THE FOLLOWING LIST MUST ALSO BE ELECTED:**

- III-a) cholestyramine;
- III-b) colestipol;
- III-c) clofibrate;
- III-d) gemfibrozil;
- III-e) lovastatin;
- III-f) pravastatin;
- III-g) simvastatin;
- III-h) probucol; and

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III-i) dextrothyroxine.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 31 is an example of a generic claim.

**IF GROUP IV IS ELECTED, A SPECIES FROM THE FOLLOWING LIST MUST ALSO BE ELECTED:**

IV-a)  $\beta$ -blocker;

IV-b) calcium channel blocker; and

IV-c)  $\alpha$ -blocker.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 33 is an example of a generic claim.

**IF GROUP V IS ELECTED, A SPECIES FROM THE FOLLOWING LIST MUST ALSO BE ELECTED:**

V-a) CART agonist;

V-b) NPY antagonist;

V-c) MC4 agonist;

V-d) orexin antagonist;

V-e) TNF agonist;

V-f) CRF agonist;

V-g) CRF BP antagonist;

V-h) urocortin agonist;

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- V-i)  $\beta 3$  agonist;
- V-j) MSH agonist;
- V-k) MCH antagonist;
- V-l) CCK agonist;
- V-m) serotonin re-uptake inhibitor;
- V-n) serotonin and noradrenaline re-uptake inhibitor;
- V-o) 5HT agonist;
- V-p) bombesin agonist;
- V-q) galanin antagonist;
- V-r) TRH agonist;
- V-s) UCP 2 or 3 modulator;
- V-t) leptin agonist;
- V-u) DA agonist;
- V-v) lipase/amylase inhibitor;
- V-w) PPAR modulator;
- V-x) RXR modulator; and
- V-y) TR  $\beta$  agonist.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 34 is an example of a generic claim.

**IF GROUP VI IS ELECTED, A SPECIES FROM THE FOLLOWING LIST MUST ALSO  
BE ELECTED:**

- VI-a) insulin;
- VI-b) sulfonylurea;
- VI-c) biguanide;
- VI-d) thiazolidinedione;
- VI-e)  $\alpha$ -glucosidase inhibitor; and
- VI-f) insulin sensitizer.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 35 is an example of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Romeo, Ph.D. whose telephone number is (703) 305-4050.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmer*

ECK  
October 1, 2002